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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR   | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/726,826      | 12/03/2003  | Andrew Thomas Forsberg | 47563.0017          | 5521             |

57600 7590 01/05/2007  
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| EXAMINER |
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SEVERSON, RYAN J

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| ART UNIT | PAPER NUMBER |
|----------|--------------|

3731

| SHORTENED STATUTORY PERIOD OF RESPONSE | MAIL DATE  | DELIVERY MODE |
|--|------------|---------------|
| 3 MONTHS                               | 01/05/2007 | PAPER         |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

## Office Action Summary

Application No.

10/726,826

Applicant(s)

FORSBERG ET AL.

Examiner

Ryan Severson

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 13 October 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 35-39 is/are pending in the application.
- 4a) Of the above claim(s) 1-34, 40 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 35-39 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 03 December 2003 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date 12/29/2003.

- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_.

## **DETAILED ACTION**

### ***Election/Restrictions***

1. Applicant's election without traverse of group III (claims 35-39) in the reply filed on 13 October 2006 is acknowledged.
2. Claims 1-34 and 40 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 13 October 2006. Applicant has cancelled claims 1-34 and 40 without traverse.

### ***Drawings***

3. Figures 1A-6 should be designated by a legend such as --Prior Art-- because only that which is old is illustrated. See MPEP § 608.02(g). Corrected drawings in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. The replacement sheet(s) should be labeled "Replacement Sheet" in the page header (as per 37 CFR 1.84(c)) so as not to obstruct any portion of the drawing figures. If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. **Claim 35 is rejected under 35 U.S.C. 102(b) as being anticipated by Nash et al. (5,662,681).** Nash et al. reference discloses the method substantially as claimed, including providing a device with a carrier tube (102), filament (34), anchor (32), and sealing plug (30) wherein the anchor is seated in a multilevel nest (see Figure1). Nash et al. reference further discloses the device is inserted into a percutaneous incision (see Column 6, Lines 57-60), the anchor is deployed (see Column 6, Lines 62-66), withdrawing the device from the incision (see Column 7, Lines 10-13), and tamping the sealing plug toward the anchor (see Column 7, Lines 43-51). The nest area of Nash et al. reference is interpreted to be the area that is initially deposited within the bypass tube (104). As shown in figure 1, the area of the carrier tube (102) within the bypass tube (104) has multiple levels. Also shown in figure 1 is a gap between the anchor and the nest.

5. **Claims 37 and 38 are rejected under 35 U.S.C. 102(b) as being anticipated by Nash et al. (5,662,681).** Nash et al. reference discloses the method substantially as claimed, including providing a gap between a carrier tube (102) and the anchor (32) by creating a multi-level nest in the carrier tube. The anchor is initially seated in the nest (see Figure 1).

6. **Claims 37 and 39 are rejected under 35 U.S.C. 102(b) as being anticipated by Bonutti (5,814,073).** Bonutti reference discloses the method substantially as claimed, including providing a gap between a carrier tube (54) and the anchor (22) by creating a multi-level nest in the carrier tube (see Figure 10). The nest of Bonutti reference is interpreted to be multi-level because it has a different diameter at it's distal-most point than it does along the majority of it's body portion. The introducer sheath acts as a one-way valve to prevent the anchor from passing back into the sheath because it has a tip with resilient members. The resilient members are capable of closing upon passage of the anchor there through.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

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7. **Claim 36 is rejected under 35 U.S.C. 103(a) as being unpatentable over Nash et al. (5,662,681) as applied to claim 35 above, and further in view of Bonutti (5,814,073).** Nash et al. reference discloses the method substantially as claimed as has been applied to claim 35 above. However, Nash et al. reference does not disclose sliding a tip of an insertion sheath into a gap formed between the anchor and the nest during anchor deployment. Attention is drawn to Bonutti reference, which teaches an introducer sheath (30) may have a resilient tips (see Column 6, Lines 53-56) which can move from open (when the anchor is being passed there through) to closed (upon passage of the anchor through the tip of the introducer sheath) positions to prevent the anchor from accidentally passing back into the introducer sheath preventing proper deployment. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use the introducer sheath with resilient tips of Bonutti reference with the closure device of Nash et al. reference to prevent the anchor from accidentally passing back into the introducer sheath preventing proper deployment.

8. Furthermore, Nash et al. reference states the closure device may be used with any typical introducer sheath (see Column 4, Lines 24-29). The tip of the insertion sheath would slide into a gap between the anchor and the nest because the tip of the sheath is resilient. The resiliency will cause the tips to conform to the shape it is compressed around, thereby filling the gap of Nash et al. reference when that point is reached.

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***Conclusion***

9. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. See form PTO-892.
10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ryan Severson whose telephone number is (571) 272-3142. The examiner can normally be reached on Monday - Thursday 7:00 - 5:30.
11. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on (571) 272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.
12. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Ryan Severson  
December 11, 2006



ANH TUAN T. NGUYEN  
SUPERVISORY PATENT EXAMINER

12/22/06